

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/17122020.9

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Guangzhou Decheng Biotechnology Co., LTD

**Room 218, Building 2, No.68,Nanxiang Road,Science City,
Huangpu District, 510000,Guangzhou P.R.China.**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2902/2020**



Issued on: 17/12/2020

Valid until: 16/12/2021


Authorized Signatory
CMC Medical Devices & Drugs SL

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ANNEX I Medical Device Products

2019-nCoV Ag & FLU A/B COMBO Rapid Test(Immunochromatography)

2019-nCoV Ag Salvia Rapid Test Card(Immunochromatography)

2019-nCoV Ag Salvia Rapid Test Cup(Immunochromatography)

2019-nCoV Ag Salvia Rapid Test Kit(Immunochromatography)

**2019-nCoV Ag Saliva Rapid Test Kit
(Fluorescence Immunochromatographic Assay)**

**2019-nCoV Ag Quantitative Test Kit
(Fluorescence Immunochromatographic Assay)**

CE